REMARKS

Claims 1-42 are pending in the present application. Claims 1-4, 6-11, 13, 15-22, 25, 27-30, and 32-40 are currently amended. Amended claims 1, 2, 3, 4, 22, and 25 more clearly define the subject matter of a high-affinity H_3 receptor antagonist, inverse agonist or partial agonist. Support for the amendments to claims 1, 2, 3, 4, 22, and 25 are found in the specification at, e.g., page 18, line 16. Amended claims 1-4, 6-11, 13, 15-22, 25, 27-30, and 32-40 correct minor editorial errors, provide proper antecedent basis, and/or provide clarity and consistency in defining the present invention that the Applicants deem as theirs. No new matter has been added.

The Office has required restriction among seven (7) groups of inventions because allegedly the groups of inventions are not so linked as to form a single inventive concept under PCT Rule 13.1. The alleged seven (7) groups of inventions are:

Group I, claims 1 and 12-17, drawn to a pharmaceutical composition comprising a compound which is a serotonin reuptake inhibitor, and a second compound, which is a H_3 receptor antagonist, inverse agonist or partial agonist;

Group II, claims 2 and 31-32, drawn to a pharmaceutical composition comprising a compound which is both a H_3 receptor antagonist, inverse agonist or partial agonist and a serotonin reuptake inhibitor;

Group III, claim 3, drawn to a method of augmenting and/or providing faster onset of the therapeutic effect of a serotonin reuptake inhibitor, comprising administering to a patient in need thereof a therapeutically effective amount of a H_3 receptor antagonist, inverse agonist or partial agonist;

Group IV, claims 4, 5-11, 18-21, drawn to the method of treating depression or an affective disorder, comprising administering a therapeutically effective amount of a pharmaceutical composition described in Group I;

Group V, claims 26-30, 33-36 and 39-40, drawn to the method of treating depression or an affective disorder, comprising administering to a patient a therapeutically effective amount of a pharmaceutical composition described in Group II;

Group VI, claims 22-24 and 37-38, drawn to a method of identifying compounds useful for the treatment of depression or an affective disorder; and

Group VII, claims 25 and 41-42, drawn to a compound that inhibits serotonin reuptake and has an IC_{50} value below 50 nM; and has an affinity to the H_3 receptor. See pages 3-4 of the Office Action. The Office further requires an election of species. See pages 7-8 of the Office Action.

Applicants hereby elect, with traverse, Group I, i.e. claims 1 and 12-17, and citalopram (the first (1^{st}) species compound of claim 16), and thioperamide (the first (1^{st}) species compound of claim 17). Should the Examiner find the elected product claims allowable, Applicants respectfully request that the method claims of Group IV, i.e. claims 4, 5-11, 18-21, be rejoined with the product claims in accordance with 37 C.F.R. 1.104. Applicants note that claims 33-36 are directed to the subject matter of Examiner's Group IV. Applicants hereby elect anxiety disorders (the first (1^{st}) species of claims 33 and 35) to be examined with Group IV.

Applicants traverse the requirement for restriction because, as will be appreciated, even if the Office considers the Groups of claims and species of compounds or disorders as lacking unity of invention, the Office has failed to meet its burden of establishing that the claims and species of compounds of the present invention lack a common special technical feature over the prior art.

Claims in different categories and species of compounds have unity if there is a special technical feature common to all the claims or species of compounds. However, if the special technical feature is known in the art, unity would be lacking because there would not be a special technical feature common to all the claims or species of compounds.

Applicants point out that Groups I-VII are unified by the technical feature of a combination of a serotonin reuptake inhibitor (SRI) and a high-affinity H_3 receptor antagonist, inverse agonist or partial agonist. Applicants maintain that the combination is not disclosed in the prior art, and therefore the technical relationship among the claims as a whole is Applicants' contribution over the prior art.

Single General Inventive Concept

PCT Rule 13.1 recites in part: "The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ...."

Applicants maintain that the single inventive concept of the subject application is the combination of an SRI and a high-affinity H_3 receptor antagonist, inverse agonist or partial agonist.

Contribution Over the Prior Art

PCT Rule 13.2 recites:

> Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Applicants unexpectedly discovered that administration of both an SRI *and* a high-affinity H_3 receptor antagonist, inverse agonist or partial agonist, in contrast to the administration of one drug alone, significantly elevates serotonin (5-HT) levels in the brain, as measured *in vivo*. (See, e.g., page 29, line 31 through page 30, line 15 of the present application.)

The present application illustrates that a high-affinity H_3 receptor antagonist alone does not induce any effect on serotonin levels. Yet the effect of the combination is greater than with the SRI alone. Hence, the special technical feature of the *combination* described in Applicants' claimed invention is a contribution over the prior art.

International Preliminary Examination Report (IPER)

It is respectfully brought to the Examiner's attention that the decision with respect to unity of invention rests with the International Searching Authority or the International Preliminary Examining Authority (see, e.g., §10.05 of Chapter 10, Unity of Invention, PCT Search and Preliminary Examination Guidelines (2004), p. 75.)

Here, the International Searching Authority did not find a lack of unity of invention for PCT/DK04/000862, the International Application on which the present [national stage] application is based (see, e.g., the attached June 20, 2006 International Preliminary Report on Patentability.)

The International Searching Authority's decision, therefore, further supports Applicants' position that the restriction of Groups 1-42 is improper.

Conclusion

Since the Examiner has not established that the special technical feature of the present application is known (e.g., by providing a prior art teaching), the technical feature is a contribution over the prior art, and thus, the present invention has unity.

Reconsideration of the application is respectfully requested and an early and favorable action on the merits of the application is kindly solicited.

The Commissioner is hereby authorized to charge any fee or underpayment thereof or credit any overpayment to deposit account no. **503201**. The Office is invited to contact the undersigned if an interview would facilitate allowance of the claims.

Respectfully submitted,

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